

S/N 10/010,066

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: David A. Schwartz et al.

Examiner: Unknown

Serial No.: 10/010,066

Group Art Unit: Unknown

Filed: December 7, 2001

Docket: 875.010US2

Title: VARIANT TLR4 NUCLEIC ACID ANALOGS AND USES THEREOF

INFORMATION DISCLOSURE STATEMENT

Assistant Commissioner for Patents  
Washington, D.C. 20231

In compliance with the duty imposed by 37 C.F.R. § 1.56, and in accordance with 37 C.F.R. §§ 1.97 *et. seq.*, the enclosed materials are brought to the attention of the Examiner for consideration in connection with the above-identified patent application. Applicants respectfully request that this Information Disclosure Statement be entered and the documents listed on the attached Form 1449 be considered by the Examiner and made of record. Pursuant to the provisions of MPEP 609, Applicants request that a copy of the 1449 form, initialed as being considered by the Examiner, be returned to the Applicants with the next official communication.

Pursuant to 37 C.F.R. § 1.97(b), it is believed that no fee or statement is required with the Information Disclosure Statement. However, if an Office Action on the merits has been mailed, the Commissioner is hereby authorized to charge the required fees to Account No. 19-0743 in order to have this Information Disclosure Statement considered.

Pursuant to 37 C.F.R. § 1.98(d), copies of the listed documents are not provided as these references were previously cited by or submitted to the U.S. Patent Office in connection with Applicants' prior U.S. application, Serial No. 09/329,515, filed on June 10, 1999, which is replied upon for an earlier filing date under 35 U.S.C. § 120.

The Examiner is invited to contact the Applicants' Representatives at the below-listed telephone number if there are any questions regarding this communication.

Respectfully submitted,

DAVID A. SCHWARTZ ET AL.

By their Representatives,

SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A.  
P.O. Box 2938  
Minneapolis, MN 55402  
(612) 373-6959

Date

March 22, 2002

By

Janet E. Embretson

Janet E. Embretson  
Reg. No. 39,665

CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail, in an envelope addressed to: Commissioner of Patents, Washington, D.C. 20231, on this 23 day of March, 2002.

Anna G. Dunbar

Name

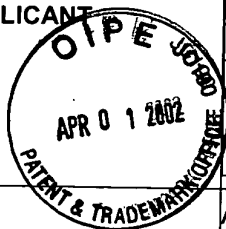
Signature

Anna G. Dunbar

Substitute for form 1449A/PTO

Approved for use through 10/31/2002, OMB 551-0001  
US Patent & Trademark Office: U.S. DEPARTMENT OF COMMERCE  
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)



Complete if Known

Application Number	10/010066
Filing Date	28, 2002
First Named Inventor	Schwartz, David
Group Art Unit	0
Examiner Name	Unknown

Sheet 1 of 2

Attorney Docket No: 00875.010US2

**US PATENT DOCUMENTS**

Examiner Initial *	USP Document Number	Publication Date	Name of Patentee or Applicant of cited Document	Class	Subclass	Filing Date If Appropriate
--------------------	---------------------	------------------	---	-------	----------	----------------------------

**FOREIGN PATENT DOCUMENTS**

Examiner Initials*	Foreign Document No	Publication Date	Name of Patentee or Applicant of cited Document	Class	Subclass	T <sup>2</sup>
	WO-98/50547	11/12/1998	Hardiman, G.T., et al	C12N	15/12	

**OTHER DOCUMENTS -- NON PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
		ARBOUR, N.C., et al., "Missense mutations of the TLR4 gene are associated with hyporesponsiveness to lipopolysaccharides (LPS) in humans", <u>Am. J. of Human Genetics</u> , Vol. 65, No. 4, (October 1999), p. A97	
		ARBOUR, N.C., et al., "TLR4 mutations are associated with endotoxin hyporesponsiveness in humans", <u>Nature Genetics</u> , Vol. 25, No. 2, (June 2000), pp. 187-191	
		BONNER, J.C., et al., "Induction of the Lung Myofibroblast PDGF Receptor System by Urban Ambient Particles From Mexico City", <u>American Journal of Respiratory Cell and Molecular Biology</u> , 19(4), (Oct. 1998), pp. 672-680	
		BRIGHAM, K.L., et al., "Endotoxin and Lung Injury", <u>American Review of Respiratory Disease</u> , (May, 1986), pp. 913-927	
		CHOW, J.C., et al., "Toll-like Receptor-4 Mediates Lipopolysaccharide-induced Signal Transduction", <u>Journal of Biological Chemistry</u> , 274(16), (April, 1999), pp. 10689-10692	
		FAVORITE, G.O., et al., "Effects Produced by the Intravenous Injection in Man of a Toxic Antigenic Material Derived From Eberthella Typhosa: Clinical Hematological, Chemical and Serological Studies", <u>Journal of Clinical Investigation</u> , (May, 1942), pp. 589-599	
		HOSHINO, K., et al., "Cutting Edge: Toll-like Receptor 4 (TLR4) - Deficient Mice are Hyporesponsive to Lipopolysaccharide: Evidence for TLR4 as the Lps Gene Product", <u>Journal of Immunology</u> , 162(7), (1999), pp. 3749-3752	
		KUHNS, D.B., et al., "Endotoxin and IL-1 Hyporesponsiveness in a Patient With Recurrent Bacterial Infections", <u>Journal of Immunology</u> , 158(8), (April, 1997), pp. 3959-3964	
		MEDZHITOV, R., et al., "A Human Homologue of the Drosophila Toll Protein Signals Activation of Adaptive Immunity", <u>Nature</u> , 388(6640), (1997), pp. 394-397	
		MEDZHITOV, R., et al., "Innate Immunity: The Virtues of a Nonclonal System of Recognition", <u>Cell</u> , 91(3), (1997), pp. 295-298	
		MICHEL, O., et al., "Effects of Inhaled Endotoxin on Bronchial Reactivity in Asthmatic and Normal Subjects", <u>Journal of Applied Physiology</u> , 66(3), (March, 1989), pp. 1059-1064	

EXAMINER

DATE CONSIDERED

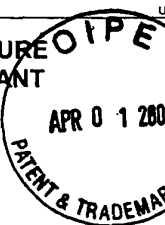
Substitute Disclosure Statement Form (PTO-1449)  
 \* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup> Applicant's unique citation designation number (optional) <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)



Complete if Known

Application Number	10/010066
Filing Date	28, 2002
First Named Inventor	Schwartz, David
Group Art Unit	0
Examiner Name	Unknown

Sheet 2 of 2

Attorney Docket No: 00875.010US2

**OTHER DOCUMENTS -- NON PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
		MICHEL, O., et al., "Severity of Asthma is Related to Endotoxin in House Dust", <u>American Journal of Respiratory and Critical Care Medicine</u> , 154(6), (Dec. 1996), pp. 1641-1646	
		POLTORAK, A., et al., "Defective LPS Signaling in C3H/HeJ and C57BL/10ScCr Mice: Mutations in Tlr4 Gene", <u>Science</u> , 282, (1998), pp. 2085-2088	
		QURESHI, S.T., et al., "Endotoxin-tolerant Mice Have Mutations in Toll-like Receptor 4 (tlr4)", <u>Journal of Experimental Medicine</u> , 189(4), (1999), pp. 615-625	
		ROCK, F.L., et al., "A family of human receptors structurally related to Drosophila Toll", <u>Proc. Natl. Acad. Sci. USA</u> , Vol. 95, (January 1998), pp. 588-593	
		SANTAMARIA, P., et al., "Involvement of Class II MHC Molecules in the LPS-Induction of IL-1/TNF Secretions by Human Monocytes", <u>Journal of Immunology</u> , 143(3), (Aug. 1989), pp. 913-922	
		SCHWARTZ, D.A., et al., "Determinants of Longitudinal Changes in Spirometric Function Among Swine Confinement Operators and Farmers", <u>American Journal of Respiratory and Critical Care Medicine</u> , 151(1), (Jan. 1995), pp. 47-53	
		SCHWARTZ, D.A., et al., "The Role of Endotoxin in Grain Dust-induced Lung Disease", <u>American Journal of Respiratory and Critical Medicine</u> , 152(2), (Aug. 1995), pp. 603-608	
		WANG, S., et al., "Effects of Inhalation of Steroids on Lung Permeability in Patients With Asthma", <u>Clinical Nuclear Medicine</u> , 20(6), (June, 1995), pp. 494-496	
		WRIGHT, S.D., et al., "CD14, a Receptor for Complexes of Lipopolysaccharide (LPS) and LPS Binding Protein", <u>Science</u> , 249(4975), (Sept. 1990), pp. 1431-1433	
		WRIGHT, S.D., "Toll, A New Prize in the Puzzle of Innate Immunity", <u>Journal of Experimental Medicine</u> , 189(4), (Feb. 1999), pp. 605-609	
		YANG, R., et al., "Toll-like Receptor-2 Mediates Lipopolysaccharide-induced Cellular Signalling", <u>Nature</u> , 395(6699), (Sept. 1998), pp. 284-288	

**EXAMINER****DATE CONSIDERED**

Substitute Disclosure Statement Form (PTO-1449)

\* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.<sup>1</sup> Applicant's unique citation designation number (optional) <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached